

readers not hired by Grace or by the Libby Claimants. To investigate the question whether the ATSDR readers agreed more often with Grace's Dr. Weill or with the CARD Clinic treating physicians in Libby, on the issue of whether or not disease was present, a comparison study was performed. Results for the 59 patients, who are clients of McGarvey, Heberling, Sullivan & McGarvey, with reads by Dr. Weill, CARD and the ATSDR are tabulated on Exh. 19 attached. Results are summarized as follows:

11	All agreed (Weill, CARD, ATSDR)
26	ATSDR agreed with CARD
16	ATSDR agreed with Weill
2	form unreadable
<u>4</u>	tie 1/1 (1 ATSDR reader agreed with each)
59	total with ATSDR readings

The result is that where Grace's Dr. Weill and CARD disagreed, the ATSDR agreed with the CARD Clinic doctors 62% of the time (26/42), and agreed with Dr. Weill only 38% of the time (16/42). Regarding the 16 where the ATSDR agreed with Dr. Weill, followup chest x-rays or CT scans as read by independent radiologists confirmed the readings by the CARD Clinic doctors on all 16 patients.

71. To compare CARD pulmonary function test (PFT) results to other pulmonary labs in northwest Montana, a study was undertaken. Certain patients who are clients of the law firm McGarvey, Heberling, Sullivan & McGarvey had independent medical exams (IMEs) or defense medical exams in the course of litigation. In Montana occupational disease cases,

the State of Montana arranges IMEs called "panel exams." In addition, the defending insurance company in a Montana occupational disease case may arrange a defense medical examination. Also certain patients had had defense exams arranged for by the Burlington Northern Santa Fe Railroad.

All such IMEs were collected. IMEs with PFTs done within six months of a CARD PFT were selected. One was excluded as the hospital concluded it was a poor test. Comparison results are summarized on Exhibit 23 for the remaining 22 patients.

The lung function test measures of forced vital capacity (FVC), total lung capacity (TLC) and diffusion capacity (DLCO) were chosen as they are the three key indicators of severity in asbestos disease. Highest FVC before or after bronchodilator was used. Individual tabulations and underlying PFT records are attached on a CD titled "PFT Comparison Study 7/23/07." On Exhibit 23, "Percent difference" means the extent to which the independent pulmonary lab numbers were above or below the results obtained by the CARD Clinic. The average difference was -3.68%, meaning that the CARD Clinic results were on the average about 3.68% higher than the independent pulmonary labs in Kalispell and Missoula. The difference is within the margin of error on lung function tests. The higher results obtained by the CARD Clinic lab may mean that technicians at the CARD Clinic were of higher competency than were those in the independent laboratories.

## **J. Other Observations**

72. Blunting or obliteration of the costophrenic angle is a chest x-ray sign. The costophrenic angle is on the side of the chest x-ray at the lower end of the lung area. No pulmonologist would use blunting to determine a diagnosis of asbestos pleural disease. Nor would a practitioner use blunting to determine severity of asbestos pleural disease.

ILO (2000) includes blunting in its scoring definition for diffuse pleural thickening. Cases with diffuse pleural thickening and no blunting fall out of the ILO (2000) scoring system and are called out as pleural plaques. This is a false result. Diffuse pleural thickening may be present in the lower, middle, and/or upper lung zones, whether or not there is blunting in the distant costophrenic angle. ILO (2000) cites no medical literature in support of its new classification for diffuse pleural thickening. No blunting requirement appeared in the earlier version of the ILO Guidelines. Light and Lee, Textbook of Pleural Diseases (2<sup>nd</sup> Ed. 2008), p.502, states that the ILO (2000) scheme is "not of much value clinically" for pleural disease.

In the CARD mortality study, of the patients who died of non-malignant asbestos disease, only 57% (42/73) had blunting of a costophrenic angle.

Definitions of diffuse pleural thickening do not require blunting of the costophrenic angle. ATS (2004), p.707, states "diffuse thickening of the visceral pleura is not sharply demarcated . . . (it) extends continuously over a

portion of the visceral pleura, often causing adhesions to the parietal pleura, involving fissures and obliterating the costophrenic angle." ATS (2004) does not include blunting in the diagnostic criteria for asbestos-related disease.

Similarly, the Frazer and Pare text, p.2804, defines diffuse pleural thickening as "with or without obliteration of the costophrenic sulci (56, 57)." The Rosenstock text, p.369, describes diffuse pleural thickening as "may involve costophrenic sulcus." The ATSDR, Case Studies in Environmental Medicine, Asbestos Toxicity (2008), p.36, defines diffuse pleural thickening as "a non-circumscribed fibrous thickening of the visceral pleura with areas of adherence to the parietal pleura and obliteration of the pleural space." ATSDR (2008) does not include blunting of the costophrenic angle in its definition. McLoud (1985), p.14, studied 185 cases of diffuse pleural thickening and found that costophrenic angle obliteration "was not a consistent accompaniment of diffuse thickening." McLoud (1985), p.16, states that blunting was often found where diffuse pleural thickening was due to effusions, however, "it is rare when the appearance is due to confluent pleural plaques" (which was 25% of the 185 cases). Lilis et al (1986), in an analysis of 1,117 insulators found 23% with measurable pleural thickening and only 13% with blunting.

Lilis et al (1991), abstract, states "the obliteration of the costophrenic angle(s), even with pleural fibrosis of limited extent, resulted in marked

decrement in FVC percentage predicted." No data are presented indicating the extent of correlation. In any event, FVC is the standard measure of severity, not blunting. There is no suggestion by the authors that blunting could ever be applied to individual patients as a measure of severity of impairment. Lilis et al (1991) did not study lung function decrements in cases of pleural thickening without blunting, and presents no comment on severity of lung function impairment in cases without blunting. Moreover, Lilis (1991) only tests one of the three measures of severity of asbestos disease, FVC, TLC and DLCO. A patient may have severe impairment with severe shortness of breath, and only one of FVC, TLC or DLCO is in the severe range. Generally, with pleural thickening there is no correlation "between radiographic severity and longitudinal loss of lung function." Yates et al (1996), p.305.

73. ILO (2000) includes a minimum requirement of 3mm thickness in its scoring definition of "diffuse pleural thickening." There is no scientific basis for a requirement of 3mm thickness to constitute "diffuse pleural thickening." Without the 3mm minimum thickness, cases of pleural thickening drop out of the ILO scoring system and are called pleural plaques. This is a false result. The earlier version of the ILO Guidelines did not have a 3mm minimum requirement for pleural thickening.

ATS (2004), Official Statement, p.707, notes that pleural thickening

"ranges in thickness from less than 1mm up to 1cm or more." No minimum thickness is required for the diagnosis of asbestos-related disease under the ATS (2004) Official Statement diagnostic criteria.

Nor is thickness of pleural thickening a measure of the severity of impairment. As noted in the letter by the President of the American Thoracic Society, "diffuse pleural scarring can be associated with greatly diminished FVC regardless of the extent or thickness of the scarring or its bilaterality." Exhibit 18. As noted, with pleural thickening there is no correlation "between radiographic severity and longitudinal loss of lung function." Yates et al (1996), p.305. Thickness of pleural thickening was included in the pleural scoring system tested in Yates et al (1996). The 3mm requirement is contrary to standard practice in diagnosing asbestos pleural disease and contrary to the ATS (2004) criteria for diagnosis of asbestos-related disease.

In the CARD mortality study, 16% (11/68) of those who died of non-malignant asbestos disease had less than a 3mm thickness in pleural thickening.

The ILO (2000) requirement of 3mm minimum thickness to call out pleural thickening is dysfunctional and has no relation to the practice of medicine.

#### 74. The National Institute for Occupational Safety and Health

certifies "B Readers" who have passed a test on selected chest x-rays which are characteristic of certain scoring levels in the ILO (2000) classification system. The ILO (2000) scoring system for chest x-rays and the B Reader certification is for research purposes. As noted in Light and Lee, Textbook of Pleural Diseases, p. 502, the ILO system "is useful for epidemiology purposes but not of much use clinically." As noted above, the ILO system of classification is never used for diagnosis, and is of no value in the classification of severity of impairment in a particular patient. Lung function tests are the gold standard for measurement of functional impairment in individual patients. And, even lung function tests often do not correlate with degree of shortness of breath or degree of hypoxia.

The ILO classification system is not used in clinical practice in the Northwest United States. The number of B Readers has declined of late. There is no B Reader in Montana.

**K. Grace/ACC Medical Criteria.**

75. I have reviewed the medical criteria in the Grace/ACC Plan of Reorganization, Trust Distribution Procedures (TDP). The TDP category for "Severe Disabling Pleural Disease", p.26, note 7, "restricts diffuse pleural thickening to cases where there is associated blunting of the costophrenic angle." The TDP requires a finding of blunting of the costophrenic angle, before the patient is determined to have "diffuse pleural thickening." This is an



incorrect definition of "diffuse pleural thickening."

Blunting or obliteration of the costophrenic angle is a chest x-ray sign. The costophrenic angle is on the side of the chest x-ray at the lower end of the lung area. No pulmonologist would use blunting to determine a diagnosis of asbestos pleural disease. Nor would a practitioner use blunting to determine severity of asbestos pleural disease.

ILO (2000) includes blunting in its scoring definition for diffuse pleural thickening. Cases with diffuse pleural thickening and no blunting fall out of the ILO (2000) scoring system and are called out as pleural plaques. This is a false result. Diffuse pleural thickening may be present in the lower, middle, and/or upper lung zones, whether or not there is blunting in the distant costophrenic angle. ILO (2000) cites no medical literature in support of its new classification for diffuse pleural thickening. No blunting requirement appeared in the earlier version of the ILO Guidelines. Light and Lee, Textbook of Pleural Diseases (2<sup>nd</sup> Ed. 2008), p.502, states that the ILO (2000) scheme is "not of much value clinically" for pleural disease.

In the CARD mortality study, of the patients who died of non-malignant asbestos disease, only 57% (38/66) had blunting of a costophrenic angle. Attached as Exhibit 17 is a letter dated February 9, 2005, titled "Preliminary Report of 79 chest x-rays reviewed relative to the Asbestos Injury Resolution Act of 2005." This study was done in response to a similar requirement of



blunting of the costophrenic angle in a draft of the asbestos bill. It is my understanding that this requirement was removed from the asbestos bill in the special provisions for Libby, as reported out of the Senate Judiciary Committee on May 26, 2005. As noted on the preliminary report in 2005, only 22 of 79 (28%) patients had blunting of the costophrenic angle.

Definitions of diffuse pleural thickening do not require blunting of the costophrenic angle. ATS (2004), p.707, states "diffuse thickening of the visceral pleura is not sharply demarcated . . . (it) extends continuously over a portion of the visceral pleura, often causing adhesions to the parietal pleura, involving fissures and obliterating the costophrenic angle." ATS (2004) does not include blunting in the diagnostic criteria for asbestos-related disease.

Similarly, the Frazer and Pare text, p.2804, defines diffuse pleural thickening as "with or without obliteration of the costophrenic sulci (56, 57)." The Rosenstock text, p.369, describes diffuse pleural thickening as "may involve costophrenic sulcus." The ATSDR, Case Studies in Environmental Medicine, Asbestos Toxicity (2008), p.36, defines diffuse pleural thickening as "a non-circumscribed fibrous thickening of the visceral pleura with areas of adherence to the parietal pleura and obliteration of the pleural space." ATSDR (2008) does not include blunting of the costophrenic angle in its definition. McLoud (1985), p.14, studied 185 cases of diffuse pleural thickening and found that costophrenic angle obliteration "was not a

consistent accompaniment of diffuse thickening." McLoud (1985), p.16, states that blunting was often found where diffuse pleural thickening was due to effusions, however, "it is rare when the appearance is due to confluent pleural plaques" (which was 25% of the 185 cases). Lilis et al (1986), in an analysis of 1,117 insulators found 23% with measurable pleural thickening and only 13% with blunting.

Lilis et al (1991), abstract, states "the obliteration of the costophrenic angle(s), even with pleural fibrosis of limited extent, resulted in marked decrement in FVC percentage predicted." No data are presented indicating the extent of correlation. In any event, FVC is the standard measure of severity, not blunting. There is no suggestion by the authors that blunting could ever be applied to individual patients as a measure of severity of impairment. Lilis et al (1991) did not study lung function decrements in cases of pleural thickening without blunting, and presents no comment on severity of lung function impairment in cases without blunting. Moreover, Lilis (1991) only tests one of the three measures of severity of asbestos disease, FVC, TLC and DLCO. A patient may have severe impairment with severe shortness of breath, and only one of FVC, TLC or DLCO is in the severe range. Generally, with pleural thickening there is no correlation "between radiographic severity and longitudinal loss of lung function." Yates et al (1996), p.305.

Blunting cannot be an element in the diagnosis of diffuse pleural thickening. Nor can blunting be a measure of severity of pleural disease. Lung function tests are the measure of severity of asbestos disease. Rosenstock text, p.370. Miles et al (2008), "Clinical consequences of asbestos-related diffuse pleural thickening, a review," p.6, states: "Few longitudinal studies exist, but these have found no correlation between radiographic severity and longitudinal loss of lung function." The use of blunting as a necessary condition to a diagnosis of diffuse pleural thickening is scientifically arbitrary. Likewise, any use of blunting to determine severity of functional impairment is scientifically arbitrary.

76. The Trust Distribution Procedures (TDP) category for "Severe Disabling Pleural Disease," p.26, requires thickness of "at least width 'a'" for diffuse pleural thickening. "Width 'a'" is defined "based on definitions as set forth in the 2000 revision of the ILO classification." ILO (2000), p.7, defines width 'a' as 3-5mm. The TDP requires a finding of thickness of width "a" (3mm) before the patient is determined to have "diffuse pleural thickening." This is an incorrect definition of "diffuse pleural thickening." No pulmonologist would use a minimum 3mm thickness as a necessary condition to a diagnosis of diffuse pleural thickening. No practitioner would use a minimum 3mm thickness to determine severity of asbestos pleural disease.

ILO (2000) provides a scoring system for chest x-rays for research purposes. Light and Lee, *Textbook of Pleural Diseases* (2<sup>nd</sup> Ed. 2008), p.502, states that the ILO (2000) scheme is "not of much value clinically" for pleural disease. ILO (2000) includes the minimum 3mm thickness in its scoring definition of diffuse pleural thickening (DPT). Cases with DPT and no 3mm thickness fall out of the ILO (2000) scoring system, and are called out as pleural plaques. This is a false result. ILO (2000) cites no medical literature in support of its new classification requiring the 3mm minimum. There was no minimum thickness in the earlier version of the ILO Guidelines. Width "a" was 0-5mm.

In the CARD mortality study, of the patients who died of non-malignant asbestos disease 84% (57/68) had the 3mm minimum thickness on chest x-ray. This is consistent with the clinical observation that many patients have died with thin diffuse pleural thickening, which is extensive. On CT scan, more pleural thickening is seen. Many more patients would qualify with the 3mm thickness if CT scans were used.

Similarly, the measurements for the 2005 CARD study of 79 sets of chest x-rays on living patients show that about 38% of the patients were excluded by a requirement of a minimum 3mm thickness. Exh. 17.

The ATS (2004) Official Statement diagnostic criteria for asbestos-related disease includes no requirement of a minimum thickness for diffuse

pleural thickening. No diagnostic definition of diffuse pleural thickening includes a requirement of a minimum thickness. In fact, ATS (2004), Official Statement, p.707, notes that pleural thickening "ranges in thickness from less than 1mm up to 1cm or more."

Nor is thickness of pleural thickening a measure of the severity of impairment. As noted in the letter by the President of the American Thoracic Society, "Diffuse pleural scarring can be associated with greatly diminished FVC regardless of the extent or thickness of the scarring or its bilaterality." Exh. 18. As noted above, with pleural thickening there is no correlation between "radiographic severity and longitudinal loss of lung function." Yates et al (1996), p.305.

The use of 3mm thickness as a necessary condition to diagnosis of diffuse pleural thickening is scientifically arbitrary. Likewise, any use of the 3mm thickness to determine severity of functional impairment is scientifically arbitrary.

77. The TDP category for "Severe Disabling Pleural Disease," p.26, defines diffuse pleural thickening as "at least extent '2' . . . based on definition set forth in the 2000 revision of the ILO classification." ILO (2000), p.7, states that extent "2 = total length exceeding one-quarter and up to one-half of the projection of the lateral chest wall." The TDP requires a finding of "extent > 25%" before the patient is determined to have "diffuse pleural

thickening." This is an incorrect definition of "diffuse pleural thickening." No pulmonologist would use "extent > 25%" as a necessary condition to a diagnosis of diffuse pleural thickening. No practitioner would use "extent > 25%" to determine functional severity of asbestos pleural disease.

In the CARD mortality study, of the patients who died of non-malignant asbestos disease 20% (13/66) did not have extent of pleural thickening greater than 25% of the chest wall. This is consistent with clinical observation that many patients have died of pleural disease without the "extent > 25%," especially when observed only on a chest x-ray. Extent of pleural thickening is better seen on CT scan. Many more patients would qualify with "extent > 25%" if CT scans were used.

The ATS (2004) Official Statement diagnostic criteria for asbestos-related disease includes no requirement of "extent > 25%" for diagnosis of diffuse pleural thickening. Nor is the extent of pleural thickening a measure of severity of impairment. As noted by the President of the American Thoracic Society, "diffuse pleural scarring can be associated with greatly diminished FVC regardless of the extent or thickness of the scarring or its bilaterality." Exh. 18. As noted above, with pleural thickening there is no correlation "between radiographic severity and longitudinal loss of lung function." Yates et al (1996), p.305.

The use of "extent > 25%" as a necessary condition to a finding of

diffuse pleural thickening is scientifically arbitrary. Likewise, any use of "extent > 25%" to describe severity of functional impairment is scientifically arbitrary.

78. The TDP excludes cases of unilateral disease. The TDP category for "Severe Disabling Pleural Disease" category requires that diffuse pleural thickening be "one component of a bilateral non-malignant asbestos-related disease." Most Libby patients who have unilateral disease later develop bilateral disease. In the CARD mortality study group of 76 non-malignant asbestos disease deaths, 1% (1/76) had unilateral disease. Exh. 7.

Asbestos pleural disease may be unilateral and severe. The President of the American Thoracic Society states: "Diffuse pleural scarring can be associated with greatly diminished FVC regardless of the extent or thickness or scarring or its bilaterality." Exh. 18.

Diffuse pleural thickening is often unilateral. A requirement in the TDP excluding unilateral cases is scientifically arbitrary, as practicing physicians may treat unilateral cases which are just as severe as bilateral cases.

Miles et al (2008), "Clinical Consequences of Asbestos-Related Diffuse Pleural Thickening: A Review," p.5, states "Approximately one-third of cases of DPT are unilateral." The Rosenstock text, p.369, states that pleural thickening is "usually bilateral." The Fishman text, p.943, states that pleural thickening can be "either bilateral or unilateral."